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EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636


21

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 08/945,731	Applicant(s) Cos, Elaissari, Mabilat, Pichot, Rodrigue And Santo
Examiner William Sandals	Art Unit 1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 25, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 6) <input type="checkbox"/> Other |

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DETAILED ACTION

Status of the Claims

1. In view of the Vacatur and Remand to the Examiner from the Board of Patent Appeals and Interferences filed on April 25, 2002, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

- 2. Claims 1-3 and 5-23 are pending. The previous final office action has been vacated. Claims 1-3 and 5-23 are rejected under new grounds below.
- 3. Claims 1 and 3 are objected to.
- 4. Claims 1, 3 and 14 are rejected under 35 USC 112, second paragraph.

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5. Claims 3, 17 and 22 are rejected as anticipated under 35 USC 102(b) over US 4,912,032 (Hoffman et al.).

6. Claims 1-3 and 5-23 are rejected as obvious under 35 USC 103(a) over US 4,912,032 (Hoffman et al.) in view of US 5,569,364 (Hooper et al.) and US 5,434,270 (Ponticello et al.), and further in view of US 5,508,164 (Kausch et al.), and further in view of US 5,206,136 (Monji et al.), and further in view of EP 161,881 (Hiroshi et al.) and US 5,225,062 (Yoshioka et al.), and further in view of US 5,280,076 (Sasaki et al.).

Claim Objections

7. Claims 1 and 3 are objected to because of the following informalities: In section "(b)", line 2, the term "absorb" is used as an equivalent term to "adsorb". Since the preamble of the claim uses the term "adsorption", changing this instance of "absorb" to "adsorb" would provide consistency in the claim language, avoiding any ambiguity. Appropriate correction is required.

8. Claim 3 is objected to because of the following informalities: In section "(b)", line 4, "10-2" is a typographical error which should read "10⁻²". Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1, 3 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 recites the limitation "the reaction medium" in section "b)", line 3. There is insufficient antecedent basis for this limitation in the claim. Changing "the reaction medium" to "the aqueous continuous phase" would cure this defect.

12. Claim 3 recites the limitation "the reaction medium" in section "b)", line 3. There is insufficient antecedent basis for this limitation in the claim. Changing "the reaction medium" to "the aqueous continuous phase" would cure this defect.

13. Claim 14 recites the limitation "the N-vinylpyridine derivatives" in line 3. There is insufficient antecedent basis for this limitation in the claim. Deleting "the" would cure this defect.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 3, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,912,032 (Hoffman et al.).

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Hoffman et al. teach at the abstract, columns 3-5, 8-14, 16, 18 and the claims, a process for isolation in aqueous phase of a nucleic acid (material) by adsorption of the nucleic acid material onto a particulate support/discontinuous phase (see column 3 to column 5 and column 11, lines 50-59). The particulate support comprises a functionalized particulate polymer obtained by polymerization of a first water soluble acrylamide monomer (or acrylamide derivative) (NIPAM) with a water soluble crosslinking agent and a second cationic and water soluble functional monomer (see column 4, lines 29-34, column 6, line 50 bridging to column 7, line 53, column 15, lines 22-59 and the figures). The polymer may have a lower critical solubility temperature (LCST) which is between 20 and 50° C (see column 7, line 3 bridging to column 9, line 23, especially column 7, lines 22-39 and figure 5). The reaction medium has a pH which is below 7, an ionic strength which is below 10^{-2} M and a temperature less than the LCST of the polymer (see example VII). Dissociating the nucleic material by desorption from the particulate support by increasing the temperature to a value greater than the LCST of the polymer (see column 5). The particulate support may have an organic or inorganic core, which may be completely or partially coated with the functional polymer (see column 11, lines 50-59). The nucleic material may be a single stranded nucleic acid which specifically binds (hybridizes) to another complementary nucleic acid (see column 10, lines 23-35). Hoffman et al. teaches at columns 13 and 14 that the LCST of a polymer may be chosen to be some value between 30° and 50° C and is produced under the control of one of skill in the art. Separating the continuous

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phase from the discontinuous phase (see example IV). Therefore, Hoffman et al. anticipates the invention of claims 3, 17 and 22.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-3, 5, 6, 9, 11-17, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,912,032 (Hoffman et al.) in view of US 5,569,364 (Hooper et al.) and US 5,434,270 (Ponticello et al.).

The claims are drawn to a process for isolation in aqueous phase of a nucleic material by adsorption of the nucleic acid material onto a particulate support/discontinuous phase. The particulate support comprises a functionalized particulate polymer obtained by polymerization of a first water soluble acrylamide (or acrylamide derivative) monomers with a water soluble crosslinking agent and a second cationic and water soluble functional monomer. The polymer may have a lower critical solubility temperature (LCST) which is between 25 and 45° C. The reaction medium has a pH which may be below 7, an ionic strength which may be below 10^{-2} M and a temperature less than the LCST of the polymer. Dissociating the nucleic material by desorption from the particulate support by increasing the temperature to a value greater than the

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LCST of the polymer. The particulate support may have an organic or inorganic core, which may be completely or partially coated with the functional polymer. The nucleic material may be a single stranded nucleic acid which specifically hybridizes to another complementary nucleic acid. The continuous phase is separated from the discontinuous phase (see example IV). The nucleic material is desorbed from the particulate support by increasing the ionic strength of the continuous phase to greater than 10^{-2} M.

Hoffman et al. teach at the abstract, columns 3-5, 8-14, 16, 18 and the claims a process for isolation in aqueous phase of a nucleic acid (material) by adsorption of the nucleic acid material onto a particulate support/discontinuous phase (see column 3 to column 5 and column 11, lines 50-59). The particulate support comprises a functionalized particulate polymer obtained by polymerization of a first water soluble acrylamide monomer (or acrylamide derivative) (NIPAM) with a water soluble crosslinking agent and a second cationic and water soluble functional monomer (see column 4, lines 29-34, column 6, line 50 bridging to column 7, line 53, column 15, lines 22-59 and the figures). The polymer may have a lower critical solubility temperature (LCST) which is between 20 and 50° C (see column 7, line 3 bridging to column 9, line 23, especially column 7, lines 22-39 and figure 5). The reaction medium has a pH which is below 7, an ionic strength which is below 10^{-2} M and a temperature less than the LCST of the polymer (see example VII). Dissociating the nucleic material by desorption from the particulate support by increasing the temperature to a value greater than the LCST of the polymer (see column 5). The particulate support may have an organic or inorganic core, which may be

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completely or partially coated with the functional polymer (see column 11, lines 50-59). The nucleic material may be a single stranded nucleic acid which specifically binds (hybridizes) to another complementary nucleic acid (see column 10, lines 23-35). Hoffman et al. teaches at columns 13 and 14 that the LCST of a polymer may be chosen to be some value between 30° and 50° C and is produced under the control of one of skill in the art. Separating the continuous phase from the discontinuous phase (see example IV).

Hoffman et al. does not teach raising the pH to desorb the nucleic material (as recited in instant claims 2 or 17) nor increasing the ionic strength above 10^{-2} M to desorb the nucleic material (as recited in instant claims 1 or 17). Hoffman et al. teaches some of the acrylamide monomers as recited in claims 12-15, but does not teach all of the acrylamide monomers as recited in claims 12-15.

Hooper et al. teach at the abstract, columns 2, 3, 6-10, example 9 and claims 14-20, the use of an acrylamide monomer which is polymerized into a particulate LCST gel to isolate and purify nucleic acids, which may be single or double stranded DNA, RNA, or oligonucleotides, (see column 3, bottom, column 8, lines 22-33, and column 10, lines 23-35). A first water soluble acrylamide (or acrylamide derivative) monomer with a water soluble polymerization agent and a second cationic and water soluble functional monomer (see columns 8-9) is used to form the polymer. The polymer has a lower critical solubility temperature (LCST) which may be between 25° and 45° C, and may be between 16° and 95° C depending upon the monomer used to form the polymer (see Table 1). Hooper et al. teach the use of a pH at most of 7 or an ionic strength at

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most of 10^{-2} M and a temperature less than the LCST of the polymer to adsorb the nucleic material (see column 3, lines 14-25, column 7, line 36 to column 8, line 11, column 10, lines 6-24, and lines 45-59 and example 9). Hooper et al. teach that the nucleic material is released from the polymer when the reaction medium has a pH above 7, or an ionic strength above 10^{-2} M, or a temperature greater than the LCST of the polymer.

Ponticello et al. teaches at the abstract a particulate LCST polymer made from acrylamide monomers which are cationic at an acid pH and insoluble and neutral in charge at a basic pH (see the summary), thereby teaching the requirement for the second cationic water soluble monomer of instant claim 1. The polymers of Ponticello et al. are taught to be useful for capturing nucleic acids.

One of ordinary skill in the art would have been motivated at the time the instant invention was made to modify the acrylamide monomers and acrylamide derived monomers, which are polymerized to form the LCST polymer which adsorbs nucleic material of Hoffman et al. with the teachings of Hooper et al. which make it obvious to modify the invention using various recited acrylamide, and acrylamide-derived monomers. Hooper et al. makes obvious the physical properties of the acrylamide polymer to release adsorbed nucleic material at elevated temperatures, or to release adsorbed nucleic material in solutions with ionic strengths greater than 10^{-2} M, or to release adsorbed nucleic material in solutions with a pH above 7. Ponticello et al. make obvious the use of various acrylamide monomers, which are obvious and well known choices within the purview of the ordinary skilled artisan in the making of LCST polymers.

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Ponticello et al. also make obvious the cationic character of various acrylic monomers used in a method of making a LCST polymer to adsorb nucleic material. Each of Hooper et al. and Ponticello et al. teach the basic chemical, biological and physical well known facts which guide the ordinary skilled artisan in the making and use of a LCST polymer in the method of Hoffman et al. Thus, one of ordinary skill in the art would have been motivated to modify the acrylamide monomers and acrylamide derived monomers which are polymerized to form the LCST polymer which adsorbs nucleic material of Hoffman et al. with the teachings of each of Hooper et al. and Ponticello et al. for the expected benefit of using acrylamide monomers to make LCST polymers which adsorb nucleic material and then release adsorbed nucleic material at elevated temperatures, at ionic strengths greater than 10^{-2} M or at a pH above 7. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Hoffman et al., Hooper et al. and Ponticello et al., who demonstrate the use of an LCST polymer to adsorb and release nucleic material.

18. Claims 1-3, 5-9, 11-17, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,912,032 (Hoffman et al.) in view of US 5,569,364 (Hooper et al.) and US 5,434,270 (Ponticello et al.) as applied to claims 1-3, 5, 6, 9, 11-17, 19 and 21-23 above, and further in view of US 5,508,164 (Kausch et al.).

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Hoffman et al., Hooper et al. and Ponticello et al. teach the invention as described above. Hoffman et al. teach the coating of polymeric supports with acrylamide polymers (see column 4, lines 5-48).

Hoffman et al., Hooper et al. and Ponticello et al. do not teach that the core of the polymer particle may be polystyrene nor comprise a magnetic compound.

Kausch et al. teach at the abstract and at column 4, lines 13-37 the well known coating of polystyrene beads with acrylamide polymer and the production of acrylamide beads comprising magnetic compounds, and that the beads are useful in the capture, isolation, preservation of structure and purification of DNA. (Kausch et al. teach at column 11, lines 50-59 that the acrylamide polymer may be used to coat particles or metals).

One of ordinary skill in the art would have been motivated at the time the instant invention was made to modify the acrylamide monomers and acrylamide derived monomers, which are polymerized to form the LCST polymer which adsorbs nucleic material, where the acrylamide is coated onto polymeric supports of Hoffman et al. , and the LCST polymers which adsorb nucleic material and then release adsorbed nucleic material at elevated temperatures, at ionic strengths greater than 10^{-2} M or at a pH above 7 of Hooper et al. and Ponticello et al. with the acrylamide polymer-coated beads comprising polystyrene or magnetic compounds, and the beads which are useful in the capture, isolation, preservation of structure and purification of DNA of Kausch et al. because Kausch et al. teach at the abstract, the use of acrylamide polymer coated beads for the expected benefit of facilitating the isolation and purification of DNA

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(nucleic material), using magnetic-core beads, saving time, improving resolution and improving purity. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Hoffman et al., Hooper et al., Ponticello et al. and Kausch et al., who demonstrate the use of an acrylamide polymer to adsorb and release nucleic material.

19. Claims 1-3, 5-17, 19 and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,912,032 (Hoffman et al.), US 5,569,364 (Hooper et al.), US 5,434,270 (Ponticello et al.) and Kausch et al. as applied to claims 1-3, 5-9, 11-17, 19 and 21-23 above, and further in view of US 5,206,136 (Monji et al.).

Hoffman et al., Hooper et al., Ponticello et al. and Kausch et al. teach the invention as described above.

Hoffman et al., Hooper et al., Ponticello et al. and Kausch et al. do not teach that the nucleic acid was a probe or a primer.

Monji et al. teach at columns 3 and 4 the use of an LCST polymer to adsorb a nucleic acid which may be a probe (ligand), and that the nucleic acid may be used in a method of synthesizing complementary nucleic acid sequences (the probe is used in this instance as a primer).

One of ordinary skill in the art would have been motivated at the time the instant invention was made to modify the acrylamide monomers and acrylamide derived monomers,

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which are polymerized to form the LCST polymer which adsorbs nucleic material, where the acrylamide is coated onto polymeric supports of Hoffman et al. , and the LCST polymers which adsorb nucleic material and then release adsorbed nucleic material at elevated temperatures, at ionic strengths greater than 10^{-2} M or at a pH above 7 of Hooper et al. and Ponticello et al. with the acrylamide polymer-coated beads comprising magnetic compounds, and the beads which are useful in the capture, isolation, preservation of structure and purification of DNA of Kausch et al. with the probe and primer of Monji et al. because Monji et al. teaches the use of nucleic acid ligands adsorbed onto LCST polymers. Monji et al. make obvious the use of an acrylamide polymer LCST gel to adsorb nucleic acid (nucleic material) which may be a probe. The probe is then used to produce complementary nucleic acids (Monji et al. uses the nucleic acid as a probe. The probe is then used as a primer to produce complementary nucleic acids). The LCST adsorbed and released nucleic acid probe of Monji et al. is useful for the expected benefit of using the nucleic material as probes in the rapid, sensitive and efficient detection of analytes in a clinical sample (see Monji et al. at columns 1-2). The probe of Monji et al. is also useful in a method of nucleic acid synthesis. Thus, the probe also has the expected benefit as being useful as a primer to facilitate the rapid, sensitive and efficient detection of analytes in a clinical sample. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Hoffman et al., Hooper et al., Ponticello et al., Kausch et al. and Monji et al. who demonstrate the use of adsorbed nucleic material in a method of isolation and detection.

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20. Claims 1-3, 5-19 and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al., Hooper et al., Ponticello et al., Kausch et al. and Monji et al. as applied to claims 1-3, 5-17, 19 and 21-23 above, and further in view of EP 161,881 (Hiroshi et al.) and US 5,225,062 (Yoshioka et al.).

Hoffman et al., Hooper et al., Ponticello et al., Kausch et al. and Monji et al. teach the invention as described above.

Hoffman et al., Hooper et al., Ponticello et al., Kausch et al. and Monji et al. do not teach that the separation of the discontinuous phase from the continuous phase may be accomplished by centrifugation, filtration, precipitation sedimentation or the application of a magnetic field as recited in instant claim 18.

Hiroshi et al. teaches at pages 5-7, 13, 17, 39-40, 44, 47-49, the use of acrylamide monomers to make particulate polymers which have critical solubility temperatures, and are pH dependent (see pages 5-7, 13, 17, 39-40, 44 and 48-49), the acrylamide polymers adsorb molecules such as nucleic acids (see pages 44-45). Materials to be released are held in gel-like polymers at low temperatures and released at high temperatures as the polymers are shrunk at high temperatures (see page 47, line 19 bridging to page 48 line 7) (LCST polymers), the discontinuous phase (composite material) may be separated from the continuous phase (liquid solution) by filtration (see page 48, lines 16-18) to facilitate analysis of the material released from the polymer gel.

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Yoshioka et al. teaches at the abstract, summary, column 6, lines 13-20 and the examples, an LCST polymer gel for the isolation and purification of nucleic acids, the nucleic acid retained in the polymer LCST gel is treated to desorb the nucleic acid by heating the gel (causing the gel to shrink), then separating the discontinuous phase (polymer gel) from the continuous phase (liquid) by methods such as centrifugation or precipitation, to purify the nucleic acid from the polymer gel which facilitates the analysis of the nucleic acid after it is released from the polymer gel.

One of ordinary skill in the art would have been motivated at the time the instant invention was made to modify the acrylamide monomers and acrylamide derived monomers, which are polymerized to form the LCST polymer which adsorbs nucleic material of Hoffman et al., Hooper et al., Ponticello et al., Kausch et al. and Monji et al. with the methods of separating the nucleic material from the solid phase LCST polymer of Hiroshi et al. and Yoshioka et al. because each of Hiroshi et al. and Yoshioka et al. teaches the desirable and beneficial separation of a substance (nucleic acid) from the LCST gel polymer by removing the liquid (continuous phase) from the gel (discontinuous phase) (see Yoshioka et al. at column 6, lines 13-20) for the expected benefit of improving the isolation and purification of the nucleic acid material by methods which are well known to those of ordinary skill in the art such as filtration, centrifugation and precipitation, thereby facilitating separation of the discontinuous phase (LCST polymer gel) from the continuous phase (liquid) to facilitate the isolation and/or analysis of the nucleic acids in the liquid. Further, a person of ordinary skill in the art would have had a

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reasonable expectation of success in the producing the instant claimed invention given the teachings of Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al. and Yoshioka et al. who demonstrate the improved isolation of nucleic material using LCST polymers.

21. Claims 1-3 and 5-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al. and Yoshioka et al. as applied to claims 1-3, 5-19 and 21-23 above, and further in view of US 5,280,076 (Sasaki et al.).

Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al. and Yoshioka et al. teach the invention as described above.

Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al. and Yoshioka et al. do not teach that the polymerization initiator is V50 as recited in instant claim 20.

Sasaki et al. teach at column 4, lines 22-29, that V50 is an initiator of polymerization for acrylamide monomers. V50 is taught to be interchangeable with other well known initiators of polymerization such as the peroxides used in the above cited references.

One of ordinary skill in the art would have been motivated at the time the instant invention was made to modify the polymerization of the acrylamide monomers and acrylamide derived monomers, which are polymerized to form the LCST polymer which adsorbs nucleic

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material of Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al. and Yoshioka et al. with Sasaki et al. because Sasaki et al. make obvious the use of the initiator of polymerization V50 for polymerization of acrylamide monomers. Sasaki et al. teach V50 to be interchangeable with other initiators of polymerization of acrylamide monomers such as the peroxides used by Hoffman et al. V50 is one of an assortment of polymerization initiators which are well known and within the purview of those of ordinary skill in the art. Thus, the V50 initiator of claim 20 is obvious over the peroxide initiators of polymerization as taught by Hoffman et al. in view of the teachings of Sasaki et al. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Hoffman et al., Hooper et al., Ponticello et al., Kausch et al., Monji et al., Hiroshi et al., Yoshioka et al. and Sasaki et al. who teach acrylamide monomers which are polymerized into LCST polymers useful for the adsorption and isolation of nucleic material.

Conclusion

22. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO


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DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.
Examiner
April 2, 2003


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600